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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,469	12/22/2000	Kyogo Itoh	0020-4792P	2449

2292 7590 04/16/2003

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EXAMINER
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YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 04/16/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

	<b>Application No.</b> 09/720,469  <b>Examiner</b> MISOOK YU, Ph.D.	<b>Applicant(s)</b> ITOH ET AL.  <b>Art Unit</b> 1642
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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### **Status**

- 1) Responsive to communication(s) filed on 18 December 2002.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### **Disposition of Claims**

- 4) Claim(s) 2,4,6,8-12 and 14-25 is/are pending in the application.
- 4a) Of the above claim(s) 9-11 and 15-24 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 2,4,6,8,14 and 25 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### **Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

### **Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### **Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13.
- 4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Misook Yu.

## DETAILED ACTION

### *Election/Restrictions*

This application contains claims 15-24 drawn to an invention nonelected with traverse in Paper No. 10. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The prosecution history indicates that applicant elected SEQ ID NO:2 as the elected species in Paper No. 10. Claims 15-24 **remain withdrawn** from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, and claims 9-11 **remain withdrawn** from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species.

The newly amended claim drawn to SEQ ID NO:44, though not the elected species, is included for examination on merits because SEQ ID NO:2 is a 9-mer peptide, amino acid #91-99 of SEQ ID NO:44, which is the full length human protein.

Claims 2, 4, 6, 8-12, and 14-25 are pending and claims 2, 4, 6, 8, 12, 14, and 25 are examined on merits as they are drawn to the extent of the elected species SEQ ID NO:2.

### *Claim Rejections - 35 USC § 112*

Rejection of claims under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** because the instant claims no longer recite the rejected limitation.

Rejection of claims because of unpredictable protein chemistry and also because of the recited limitation "derivative" under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention **is withdrawn** because protein chemistry in vitro testing

does not require undue experimentation and also because the amended claim is limited to "derivative" of defined instant SEQ ID NOs.

**Claim 14 remain rejected** under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant does not address the rejection the Office made based on the specification's lack of enablement for treating or preventing tumors using the instantly claimed product, other than saying that the amended claim is directed to method instead of "pharmaceutical". The art recognizes that prevention or treating cancer is NOT a trivial matter. Considering the state of art regarding cancer prevention and/or treatment, one skilled in the art would have reason to question the efficacy of the treatment/prevention method. In the absence of a working example or other evidence of the method's effectiveness, it is maintained that undue experimentation would be required to practice the invention as claimed.

#### ***Claim Rejections - 35 USC § 102***

Claims 2, 4, 6, 8, 12, and 25 **remain rejected** under 35 U.S.C. 102(b) as being anticipated by Price et al (1991, Proc. Natl. Sci. USA, vol. 88, pages 1903-1907).

The instant claims are interpreted as drawn to peptide per se comprising SEQ ID NO:2 (the elected species). As for claim 8 reciting "derivative", it is noted that # 2 position of SEQ IS NO:2 is phenylalanine and the C-terminus of SEQ IS NO:2 is also phenylalanine.

Applicant argues that Price et al do not teach each and every limitation of instantly claimed invention, i.e. Price et al do not disclose an isolated tumor antigen peptide that binds to an HLA antigen and is recognized by CTL. The argument is not commensurate with the scope of claims because the instant invention is drawn to peptide **comprising** SEQ ID NO:2 and Price et al teach peptide comprising the instant SEQ ID NO:2 at Fig. 1 at page 1904. Note that instant SEQ ID NO:2 is identical to amino acid #91-99 of the protein at Fig. 1 of Price et al. Although Price et al do not teach the peptide sequence amino acid #91-99 of the protein at Fig. 1 binds to HLA and

recognized by CTL, those are the inherent properties of the protein comprising the peptide.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Application/Control Number: 09/720,469  
Art Unit: 1642

Page 5

Misook Yu  
April 10, 2003

*Mary Mosher*  
**MARY E. MOSHER**  
**PRIMARY EXAMINER**  
**GROUP 1800**  
*(60)*